K020076
page 1 of 1

JAN 3 0 2002

BIOMET
CORPORATE HEADQUARTERS

## SUMMARY OF SAFETY AND EFFECTIVENESS

**Sponsor:** Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, In. 46581-0587

**Contact Person:** Tracy Bickel
(219) 267-6639

**Proprietary Name:** Patroit Protrusio Cage

**Common Name:** Acetabular Component

**Classification Name:** Hip joint metal/polymer/metal semi-constrained uncemented prosthesis (888.3358)

**Substantially Equivalent Devices:** Patriot Protrusio Cage – K001376

**Device Description:** This series of six anatomic protrusio cages is manufactured from Titanium. Each cage has two iliac flanges positioned superiorly and one ischial flange positioned inferiorly that provide supplemental screw fixation holes for attachment to the ilium and ischium. These cages, once positioned in the acetabulum and attached to the ilium and ischium, provide structural integrity to an otherwise structurally compromised joint.

The device is a single use implant intended for implantation with bone cement.

In cases where bony defects or voids exist, optional augments can be utilized to help provide additional structural support. The augments are attached to the cage by means of a locking screw.

**Intended use:** The Protrusio implants are intended for use in reconstruction of the hip joint due to disease, deformity or trauma. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery. The device is a single use implant. The Protrusio Cage is to be used in conjunction with any commercially available polyethylene acetabular cup.

**Summary of Technologies:** The Patriot Protrusio Cage material, design, sizing, and indications are similar to or identical to the predicate devices.

**Non-Clinical Testing:** Testing determined that Patriot Protrusio Cage components presented no new risks and were; therefore, substantially equivalent to the predicate device.

**Clinical Testing:** None provided as a basis for substantial equivalence.



MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 219.267.6639 ■ FAX 219.267.8137 ■ E-MAIL biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Ms. Tracy J. Bickel
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K020076
Trade Name: Patriot Protrusio Cage
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/ metal semi-porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: JDI
Dated: January 7, 2002
Received: January 9, 2002

Dear Ms. Bickel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020076
Device Name: **Patriot Protrusio Cages**
Indications for Use:

The Protrusio implants are intended for use in reconstruction of the hip joint due to disease, deformity or trauma. The devices are intended for general use in skeletally mature individuals undergoing primary and/or secondary revision surgery. The device is a single use implant. The Protrusio Cage is to be used in conjunction with any commercially available polyethylene acetabular cup.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark A. Melhem
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

000076

510(k) Number K020076